STATE OF CALIFORNIA—HEALTH AND WELFARE AGENCY PETE WILSON, *Governor*

DEPARTMENT OF HEALTH SERVICES
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October 6, 1998

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Jane Axelrad, Associate Director
Food and Drug Administration
Center for Drug Evaluation and Research
HFD-005, WOC2-6027
5600 Fishers Lane
Rockville, MD 20857

Dear Ms. Axelrad:

Re: Practice of Pharmacy Compounding

It is my understanding that as part of the Federal Food, Drug and Cosmetic Modernization Act, the US Food and Drug Administration will be convening meetings to comply with implementing practice of pharmacy compounding provisions. I am also aware that in California, pharmacies compound drugs for investigational studies. These compounded drugs may be "approved drugs", unapproved drugs, placebos, etc. Dosage forms my be oral or injectable liquids, tablets, capsules, suppositories, powders, ointments, creams, radiolabled drugs, etc. The studies may or may not be subject to "Investigational New Drug" (IND) application requirements.

I would like to have the meeting participants on the practice of pharmacy compounding committee be aware of this type of pharmacy compounding and only restrict it where patient safety may be compromised. Also, if possible, I would appreciate copies of meeting minutes as well as any proposed or final guidelines dealing with investigational drug compounding. Thank you.

Sincerely,

Raymond D Wilson, Pharm D

Raymond D. Wilson, Pharm.D
Food and Drug Scientist
Drug Safety Section.

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